K070360

KIRWAN® SURGICAL PRODUCTS

AUG - 7 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

{as required by 21 CFR, section 807.92(c)}

FOR

KIRWAN DISPOSABLE MANIFOLD TUBING SET

MODELS: 40-3600, 23 kHz, and 40-36001, 36 kHz

Common name: Irrigation / Aspiration Lines

Classification name: Unclassified

Product code: LFL.

Devices Class: Class I

These tubing sets are designed to function as Manifold Tubing for the CUSA EXcel™ Ultrasonic Aspirator System i.e., both 23 kHz and 36 kHz hand-piece models. As Manifold Tubing they link the system console to the appropriate hand-piece, providing conduits for both irrigation and aspiration of the surgical site.

Technological safety and effectiveness is established by the fact that these tubing sets do not contain any new technological risks or characteristics when compared to the legally marketed device offered here as predicate. They are manufactured according to prevailing standards and represent a technology that has existed in clinical settings for over 30-years.

There are no applicable performance standards listed for these devices under Section 514 of the Food, drug and Cosmetic Act. Nonetheless, Kirwan 40-3600, 23 kHz and 40-3601, 36 kHz Manifold Tubing devices have been tested and

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Contact: Kevin P. Prario, Regulatory Affairs Manager
Date prepared: 2/1/2007

manufactured in accordance with prevailing standards and guidelines in order to assure safety and efficacy. Kirwan manifold tubing sets have been found to comply with the requirements of the applicable sections within the following standards and guidelines;

- ISO 11137, Sterilization of health care products – Requirements for validation and routine control-radiation sterilization.
- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing.

Safety and hazard analysis has determined that the hazard conditions for the Kirwan disposable manifold tubing sets range in the low-to-moderate level and for this reason are acceptable.

Therefore, the Kirwan 40-3600, 23 kHz and 40-3601, 36 kHz Disposable Manifold Tubing Set devices are substantially equivalent in intended use, technological safety and effectiveness and performance to the following predicates;

- C3600, 23 kHz Manifold Tubing (Integra LifeSciences).
- C3601, 36 kHz Manifold Tubing (Integra LifeSciences).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kirwan Surgical Products, Inc.
% Mr. Kevin Prario
Regulatory Affairs manager
180 Enterprise Drive
Marshfield, Massachusetts 05050

AUG - 7 2007

Re: K070360
Trade/Device Name: Models: 40-3600/01, Kirwan Disposable Manifold Tubing Set
Regulatory Class: Unclassified
Product Code: LFL
Dated: July 30, 2007
Received: July 31, 2007

Dear Mr. Prario:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

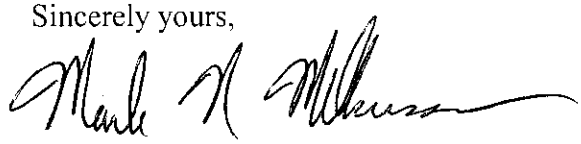
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name:

Models: 40-3600/01, Kirwan Disposable Manifold Tubing Set

Indications for Use:

These tubing sets are designed to function as Manifold Tubing for the CUSA EXcel™ Ultrasonic Aspirator System i.e., both 23 kHz and 36 kHz hand-piece models. As Manifold Tubing they link the system console to the appropriate hand-piece, providing for both irrigation and aspiration of the surgical site.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070360